EXHIBIT C

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Hon. Patti B. Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., v. Boehringer Ingelheim Corp., et al., Civil Action No. 07-10248-PBS	)	

MEMORANDUM IN SUPPORT OF UNITED STATES' MOTION FOR LEAVE TO FILE AMENDED COMPLAINT

The United States seeks leave to amend its complaint to formally include three NDCs and one HCPCS code that, although not specifically identified in the Complaint, relate to drugs already at issue in this litigation.[1] In particular, based on its review of documents produced in discovery, the United States has learned that beginning in 1999, Roxane launched newly packaged versions of Ipratropium Bromide under a "NovaPlus" label. Other than being marketed under a different label and having different NDCs, the NovaPlus Ipratropium Bromide products are identical to the Ipratropium Bromide products alleged in the Complaint. In addition, the United States learned that Medicare reimbursed Roxane's drugs under one additional Healthcare Common Procedural Coding System ("HPCPS") code not mentioned in the Complaint, "K0119." The United States seeks leave to amend its complaint to formally

[1]The relator, Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care") consents to and joins in the filing of this motion.

include the NovaPlus Ipratropium Bromide Products and the K0119 code.[2]

The only changes in the United States' proposed amended complaint (attached hereto as Exhibit 1) are that the NovaPlus Ipratropium Bromide products are listed in the schedule of "drugs and corresponding NDCs" attached as Exhibit A to the Complaint, and that K0119 appears in the list of HPCPS codes alleged in Paragraph 42. Granting the United States leave to amend its complaint will not cause undue prejudice to the defendants, as the proposed amended allegations involve the same pricing scheme already alleged by the United States, and relate to drugs that are already at issue in this litigation.

BACKGROUND

On January 18, 2007, the United States filed its Notice of Intervention and Complaint in this case. Fact discovery has been ongoing, and is scheduled to close on December 15, 2008. The complaint alleges that defendants knowingly caused the Medicare and Medicaid programs to pay false or fraudulent claims for nine drugs, including Ipratropium Bromide. See Complaint, ¶ 58. The United States attached as Exhibit A to the Complaint a schedule of "the drugs and corresponding NDCs at issue in this case." Id., ¶ 38. That schedule identifies 32 separate NDCs relating to the nine charged drugs, including the following:

- Ipratropium Bromide Inhalation Solution .02%, 25s (00054-8402-11);
- Ipratropium Bromide Inhalation Solution .02%, 30s (00054-8402-13); and
- Ipratropium Bromide Inhalation Solution .02%, 60s (00054-8402-21).

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[2]The United States maintains that theNovaPlus Ipratropium Bromide products are already included within its complaint, as they are materially identical to the Ipratropium Bromide products alleged in Paragraph 58 of the Complaint. To be cautious, the instant motion seeks to clarify this point by expressly including the NovaPlus Ipratropium Bromide in the list of drugs and NDCs attached as Exhibit A to the proposed amended complaint.

In the course of discovery, the United States learned that beginning in 1999, Roxane entered into an agreement with Novation, LLC ("Novation"), a group purchasing organization, to distribute and promote Roxane's Ipratropium Bromide Inhalation Solution .02% products under a "NovaPlus" label (the "NovaPlus Products"). Under the terms of the agreement, Roxane paid compensation to Novation for marketing assistance to place the NovaPlus Products with Novation members. The NovaPlus Products were identical to the Ipratropium Bromide products identified in Exhibit A to the Complaint, except with different NDCs and the new NovaPlus label. Roxane set the Average Wholesale Prices ("AWPs") for the NovaPlus Products, and reported the AWPs to the pricing compendia throughout the relevant time period. The AWPs Roxane reported for the NovaPlus Products were exactly the same as the AWPs Roxane reported for its ordinary Ipratropium Bromide products. See Exhibit 2 hereto. The actual prices Roxane charged for the NovaPlus Products were substantially lower than the reported AWPs, and were largely similar to the actual prices Roxane charged for its ordinary Ipratropium Bromide products.

In addition to the inclusion of the NovaPlus Products, there is one other small change in the United States' proposed amended complaint. Paragraph 42 of the Complaint alleges that the "HPCPS codes for the Roxane drugs reimbursed by Medicare at issue here are J7644, J7645, K0518, and J7500." During discovery, the United States learned that Roxane's Azathioprine products were reimbursed by the Medicare program under an additional HPCPS code not mentioned in the complaint, "K0119." The proposed amended complaint includes an amended

Paragraph 42 to add K0119.[3]

ARGUMENT

"Rule 15(a) provides that a party may amend its pleading with the court's leave, and that the court should freely give leave when justice so requires." See ACA Financial Guaranty Corp. v. Advest, Inc., 412 F.3d 46, 55 (1st Cir. 2008) (internal citation omitted). The grant or denial of a motion to amend is within the discretion of the court. See Ondis v. Barrows, 538 F.2d 904 (1st Cir. 1976). Leave to amend should be denied only for a valid reason such as "bad faith by the moving party, unwarranted delay, or undue prejudice to the opposing party." See Executive Leasing Corp. V. Banco Popular de Puerto Rico, 43 F.3d 66, 70 (1st Cir. 1995). The analysis of whether to permit amendment "focuses mostly on the bad faith of the moving party and the prejudice to the opposing party." In re iBasis, Inc. Derivative Litigation, 551 F. Supp. 2d 122 (D. Mass. 2008) (citing O'Connell v. Hyatt Hotels of Puerto Rico, 357 F.3d 152, 155 (1st Cir. 2004)). "Delay that is neither intended to harass nor causes any ascertainable prejudice is not a permissible reason, in and of itself, to disallow an amendment of a pleading." See Carmona v. Toledo, 215 F.3d 124, 136 (1st Cir. 2000).

Here, the United States seeks to amend its complaint in order to formally include three NDCs and one HPCPS code that relate to drugs already at issue in the litigation. Significantly, the proposed amended allegations do not add any new parties or any new theories of liability to the case, and do not change the underlying factual allegations. Rather, they simply make clear that the United States is seeking damages for all versions of Roxane's Ipratropium Bromide

[3]The K0119 code was used in addition to the J7500 code until March 31, 2000, when it was discontinued.

Inhalation Solution .02% products. In similar circumstances in the New York Counties case, this Court held that plaintiffs could amend their complaint to add new NDCs for drugs already at issue in the litigation. See Exhibit 3 hereto (attaching portions of the July 26, 2007, motion hearing), at pp 9 and 38-39. In the Dey case, the United States also recently discovered that the defendants had marketed several of the subject drugs under different NDCs than those mentioned in the complaint. The Dey defendants consented in writing to the United States filing an amended complaint pursuant to Rule 15(a)(2). Although the United States sent Roxane its proposed amended complaint, and a copy of the Court's July 26, 2007 Order in the New York Counties case, Roxane has refused to give consent.

The United States acted promptly to amend its complaint once it discovered that the NovaPlus Products were the same as Roxane's Ipratropium Bromide Inhalation Solution .02% products, and Roxane reported the same inflated AWPs for both its ordinary Ipratropium Bromide products and the NovaPlus Products. The proposed amendment should not have come as any surprise to the defendants. The United States has consistently taken the position that if Roxane marketed any of the charged drugs under different NDC numbers than those listed in the complaint, then such alternative NDCs are properly within the scope of the complaint. As Roxane plainly knew that it marketed its Ipratropium Bromide Inhalation Solution .02% products under the NovaPlus label, it will not suffer any prejudice from the complaint being amended to include the NovaPlus Products. See Buder v. Merrill Lynch, Inc., 644 F.2d 690, 694 (8th Cir. 1981) ("Where the facts on which a previously unasserted claim is based are all known

or available to all parties, there is no prejudice in allowing an amended complaint").[4]

Moreover, the proposed amended complaint will not significantly add to the defendants' discovery obligations, as the only additional discovery likely to be necessary is the transactional data for the NovaPlus products. See Federal Deposit Ins. Corp. v. Consolidated Mortg. and Finance Corp., 805 F.2d 14, 16 (1st Cir. 1986) (allowing motion to amend where amended complaint did not require additional time for discovery or additional time to prepare for trial); Burns & Roe, Inc. v. Central Maine Power Co., 659 F.Supp. 141, 143 (D. Maine 1987) (granting motion to amend where issues raised by amended complaint "are primarily legal ones" and "little or no additional discovery will be necessary to posture them for adjudication"). In addition, the proposed amended complaint will not require any change in the defendants' defenses or trial strategies as Roxane's marketing of its Ipratropium Bromide products was already fully at issue in the case. The inclusion of additional versions of the same Ipratropium Bromide products will not require the defendants to conduct any additional discovery, and does not alter the legal landscape of the case.

Wherefore, the United States respectfully requests that the Court grant leave to file its First Amended Complaint.

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[4] See also Medigen of Kentucky, Inc. V. Public Service Com'n of West Virginia, 985 F.2d 165, 168 (4th Cir. 1993) (Allowing motion to amend; no prejudice to opposing counsel where proposed amended complaint "did not change the substance of the case"); Nance v. Gulf Oil Corp., 817 F.2d 1176, 1179-80 (5th Cir. 1987) (allowing amended complaint to introduce strict liability claim; defendant failed to articulate prejudice because the strict liability cause of action was an alternative theory of recovery substantially similar to claims already in the case).

Respectfully submitted,

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Dated: October 20, 2008

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO AMEND COMPLAINT" to be served on all counsel of record via electronic service pursuant to the Case Management Order by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ James J. Fauci
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Dated: October 20, 2008